REMARKS

This paper responds to the Office Action mailed on September 29, 2009.

Applicants note that the U.S. Specification as filed (U.S.S.N. 10/572,502, filed March 17, 2006) and the Substitute Specification filed the same day with the Preliminary Amendment have different line and paragraph numbering schemes. To avoid confusion, Applicants will refer to the appropriate page numbers and paragraph numbers in this application's corresponding U.S. Patent Application Publication 2007/0071816 (March 19, 2007).

Status of Claims

Claims 25-40 have been amended; claim 41 has been canceled; and new claim 42 has been added. As a result, claims 25-40, and 42 are now pending in this application.

Claim 25 has been amended to recite that the drug delivery system is an oral drug delivery system in which the core comprises an active ingredient composition region and a swellable or reactive composition region. There is a coating surrounding the core; and the swellable or the reactive composition is located in an immediate vicinity of preselected portions of the coating in order to be in communication with the said preselected portions of the coating. The active ingredient composition is in the vicinity of another portion of the coating. Support for this amendment is found throughout the specification. These include embodiments wherein the two regions are for example, as two separate layers or where one of them is present in the form of an "in-lay" and where the respective regions are in contact with portions of the coating. When the orally administrable drug delivery system contacts the aqueous environment, water enters the core by the natural process of diffusion/permeation from the aqueous environment into the core through the coating. In embodiments where the coating is water impermeable, water enters the core through a passageway in the coating. The imbibition of water by the swellable composition or reactive composition enables them to be "in communication with" i.e., interact with the preselected portions of the coating, resulting in the removal of the preselected portion of the coating but not the removal of the remaining portion of the coating. Thus a cup shaped structure

is formed, the cup containing the active ingredient composition that releases the active ingredient into the aqueous environment.

Claims 26-40 have been amended to conform to U.S. patent practice for dependent claims by replacing "An" with "The." Claims 26-39 have also been amended to correct grammatical errors.

Claim 27 has been amended to recite that the one or more passageways are present on the preselected portions of the coating. Support for this amendment is found at page 4, paragraph [0082] and in Fig. 1.

Claim 28 has been amended to recite that the coating is impermeable to the pharmaceutically active ingredient. Support for the term "pharmaceutical" is found at page 6, paragraph [0100] wherein the equivalent terms "drug delivery system" and "pharmaceutical composition" are used.

Claim 31 has been amended to recite that the active ingredient in the one or more layers may be the same or different.

Claim 33 has been amended to recite additional features of the active ingredient composition.

Claim 36 has been amended to recite "one or more" wicking agents. Support for this term is found at page 3, paragraph [0043] (item xvii) where the plural term "wicking agents" is used.

Claim 37 has been amended to recite "one or more" osmogents. Support for this term is found at page 3, paragraph [0044] (item xviii) where the plural term "osmogents" is used.

Claim 39 has been amended to recite that the drug delivery system may comprise a second, pH dependent outer coating. Support for this term is found at page 7, paragraph [0108] where pH dependent coatings are described.

Claim 40 has been amended to depend from claim 25.

Claim 41 has been cancelled.

Claim 42 has been added to recite that the drug delivery system is an oral drug delivery system in the form of a multilayer coated tablet in which the core comprises an active ingredient composition and a swellable or reactive composition. The active ingredient composition may be

in at least one layer and may comprise one or more active ingredients. Support for these features is found in page 6, paragraphs [0101] to [0104]. Additional support for a multilayer structure of the tablets is found in Figure 1(c). There is a coating surrounding the core; and the swellable or the reactive composition is located in a layer in the immediate vicinity of preselected portions of the coating in order to be in communication with the preselected portions of the coating. The active ingredient composition layer is in the vicinity of another portion of the coating. Support for this amendment is found throughout the specification.

In view of the extensive amendments to the claims, Applicants are also attaching a "clean" copy of the pending claims.

No new matter is added with these amendments

In view of the present amendments and remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections and allowance of all claims.

Interview Summary

Applicants thank Examiners Micah-Paul Young and Eric E. Silverman for graciously extending the courtesy of a helpful in-person interview with Applicant Dr. Nitin B. Dharmadhikari and Applicants' representatives, Gary J. Speier and Louis M. Leichter, on January 12, 2010.

During the interview, Applicant Dr. Dharmadhikari demonstrated the invention for the Examiners and presented a video and slide presentation of the invention. The demonstration and exhibit explained the mechanism of the instant claims. The peeling and surface mechanics were explained, and the Examiners agreed that these mechanisms were not present in the prior art of record. Applicants agreed to consider claim amendments that more clearly convey the specific peeling and surface mechanism shown in the exhibition. The Examiners agreed that the prior art of record would fall and that a new search would be conducted. Subsequent to the interview, Applicants mailed a CD of the video and slide presentation to Examiner Young to be included in the file as an exhibit explaining the mechanics claimed.

Applicants particularly thank Examiners Young and Silverman for suggesting the term "in communication with" to describe the interaction of the swellable or reactive composition with the preselected portion of the coating. Applicants also wish to thank Examiners Young and Silverman for suggesting that various embodiments be recited in independent claims.

Applicants' Invention

For clarity, applicants are including a description of the mechanics of operation of the invention. When the orally administrable drug delivery system contacts the aqueous environment, water enters the core by the natural process of diffusion/permeation from the aqueous environment into the core through the coating. In embodiments where the coating is water impermeable, water enters the core through a passageway in the coating. The imbibition of water by the swellable composition or reactive composition enables them to be "in communication with" i.e., interact with the preselected portions of the coating resulting in the removal of the preselected portion of the coating but not the removal of the remaining portion of the coating. Thus a cup shaped structure is formed, the cup containing the active ingredient composition that releases the active ingredient into the aqueous environment.

Rejection Claims under 35 U.S.C. § 102

Claims 25-30, 32, and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hettche (U.S. Patent 5,271,946, hereafter '946).

The Office Action asserts that the '946 patent teaches an oral drug delivery system comprising at least a coated core comprising an active agent and at least a coating surrounding the core. The coating comprises pore-forming agents such as carbonates. The core comprises gas generating agents. Other features present include pH dependent semipermeable polymers, swellable polymers, osmotic agents, and wicking agents. The Office Action further asserts that the coating layers of the '946 patent would reliably be fully removed in the appropriate aqueous environment.

In so far as it applies to the claims as presently amended, Applicants respectfully traverse this rejection.

It is axiomatic that for an anticipation or lack of novelty rejection to stand, each and every claimed element (or feature) must be explicitly or implicitly described in a single Section 102(b) reference, *In re Lange* 209 USPQ 288, at 293 (CCPA, 1981) and *Ex parte Levy* 17 USPQ2d 1461 (PTOBPAI, 1990).

Applicants respectfully submit that pending claims 25-30, 32, and 34-40, as amended, are not anticipated by Hettche '946 because that document does not teach each and every aspect of the presently claimed invention. Specifically, Hettche et al. does not teach the removal of a preselected portion of the coating in response to the swelling or reacting of a swellable or reactive composition or mixture located within the tablet and in communication with the preselected portion of the coating. Also Hettche et al does not disclose a system wherein the swellable or the reactive composition is located in an immediate vicinity of preselected portions of the coating in order to be in communication with said preselected portions of the coating; and the active ingredient composition is in the vicinity of another portion of the coating.

Instead, Hettche et al. teaches several methods of drug (i.e., azalastine) release from a tablet, such as; 1) binding the drug to physiologically acceptable ion exchange resins followed by encapsulation (column 3, lines 29-62); 2) coating of tablets with various substance or mixtures (column 3, line 63 to column 5, line 8); 3) coating the tablet with microporous osmotically active substances (column 5, line 9 to column 7, line 2) including boring a hole in the tablet to adjust the release rate; 4) embedding azalastine in various binders (column 7, lines 3 to column 8, line 55) including swelling agents. All of the methods described by Hettche et al. provide a uniform coating on the surface of the tablet. The entire coating is involved in the release of the drug. Hettche et al. does not prepare a tablet with at least one preselected portion of the coating that is intentionally formulated to rupture and release the active ingredient in a controlled manner, leaving at least one surface intact.

Independent claims 25 and 42 recite the removal of only a preselected portion of the coating to release a drug. Because Hettche et al. does not teach the removal of only a preselected

portion of the coating to release a drug it cannot anticipate independent claims 25 and 41. In addition, Hettche et al. does not anticipate claim 25 and claim 42 because it does not disclose a system wherein the swellable or the reactive composition is located in an immediate vicinity of preselected portions of the coating and the active ingredient composition is in the vicinity of another portion of the coating.

Inasmuch as claims 27-30, 32, and 34-39 depend from claim 25, they too are not anticipated., In view of the above remarks, Applicants respectfully request withdrawal of the rejection of pending claims 25-30, 32, and 34-40 under 35 U.S.C. 102(b) as anticipated by Hettche et al.

Claim 41 has been cancelled. The rejection of claim 41 is therefore moot.

Rejection Claims under 35 U.S.C. § 103

Claims 25-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Hettche (U.S. Patent 5,271,946 hereafter '946) in view of Burnside et al (U.S. Patent 6,322,819, hereafter '819).

The Office Action asserts that the '946 patent discloses a formulation comprising a coated tablet wherein the core comprises swellable polymers and a coating completely surrounds the core. The core further comprises swellable polymers, wicking agents, and osmotic agents. The Office Action admits that the '946 patent does not teach further active drug coating layers in the same formulation and relies on Burnside et al. ('819) for this feature. The Office Action asserts that Burnside et al. discloses oral formulations comprising a core having multiple layers, including protective layers and additional drug layers. The drugs in these layers may be the same or different. The Office Action asserts that it would have been obvious to add additional layers of drugs to the coated cores described in the ''946 patent to provide both immediate relief and longer timed relief. The Office action concludes that it would have been obvious to combine the added release layer of the '819 patent with the coated cores of the '946 patent to expand the administration options for the formulation and to achieve a stable controlled release formulation.

In so far as it applies to the claims as presently amended, Applicants respectfully traverse this rejection.

The deficiencies of Hettche et al. ('946) described above are incorporated by reference and need not be repeated. The addition of Burnside et al. ('819) does not overcome the deficiencies of Hettche et al. Burnside et al. discloses a multi-coated tablet that is capable of controlled release by dissolution of various coatings. The coatings are uniformly distributed around the surface or the tablet (Figs. 2A, 2B, and 2C). Upon dissolution, the entire coating of the tablet is removed (Figs. 2B and 2C).

Burnside does not create a tablet with a surface, a portion of coating of which is intentionally formulated to rupture and release the active ingredient from a specified portion of the tablet in a controlled manner. All examples show uniform distribution of the active ingredient in a tablet.

Thus, neither Hettche et al, nor Burnside et al., either alone or in combination, provide any teaching, suggestion, motivation, or guidance to prepare Applicants' invention.

Accordingly, Applicants submit that pending claims 25, 27-30, 32, 34-39, and 41 are not obvious over Hettche et al. in view of Burnside et al. under 35 U.S.C. § 103(a). Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 41 has been cancelled. The rejection of claim 41 is therefore moot.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6961 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date: March 19, 2010

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 19 day of March 2010.

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